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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,818	04/17/2001	Kelvin G.M. Brockbank	105452	5532

25944 7590 12/16/2004

OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835,818

Applicant(s)

BROCKBANK ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 15-19, 29-32 and 36-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13, 15-19, 29-32 and 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to an amendment filed 9/29/04. Claims 1-10, 14, 20-28 and 33-35 have been cancelled. Claims 37-44 have been added. Claims 11, 15, 16, 18 and 29 have been amended. Claims 11-13, 15-19, 29-32 and 36-44 are pending in this instant application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicant's amendment and therefore, this action is not final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13, 15-19, 29-32 and 36-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-18 of copending Application No. 10/099,943. **This is a new rejection.**

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The instant claims are drawn to a cryopreservation compound comprising a cyclohexanediol such as 1, 4 cyclohexanediol or 1,3 cyclohexanediol in a concentration of 0.05 to 2.0 M and at least one additional cryoprotectant in the concentration of 0.1 to 10 M. Additionally, the cryopreservation compound comprises anti-freeze glycoprotein or an anti-freeze protein. The claims of US 6,596,531 are directed at methods of thawing cryopreserved cells. In order to practice the claimed methods for 6,596,531, the skilled artisan would necessarily have to look to the specification in order to determine the cryopreservation compounds and methods of cryopreservation considered as usable for the claimed methods. For cryopreservation, the specification discloses that the cells must be exposed to 1, 4 cyclohexanediol or 1,3 cyclohexanediol in a concentration of 0.05 to 2.0 M and at least one additional cryoprotectant in the concentration of 0.1 to 10 M. Additionally, the cryopreservation compound comprises anti-freeze glycoprotein or an anti-freeze protein (see e.g. col 4, line 3-65). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Therefore, in order to practice the claimed invention in 6,596,531, one of ordinary skill in the art would have to read those parts of the specification that provide support for the claimed invention. It would have been prima facie obvious to one of skill in the art to use the cryopreservation compounds disclosed in the instant specification to cryopreserve the cells prior to thawing. It would have been obvious to one of skill in the art to use these compounds given the success of these compositions in the freezing and thawing of cells as disclosed in 6,596,531.

Claims 11-13, 16, 29, 40 and 44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-18 of copending Application No. 10/099,943. **This rejection is maintained for reasons of record in the office action filed 12/23/03 and 6/3/04 and restated below and has been extended to newly added claims 40 and 44. Upon reconsideration, the rejection has been applied to claim 29.**

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims 15-18 of U.S. application 10/099,943. That is, the cited claims of U.S. application 10/099,943 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, both the instant invention and the U.S. application 10/099,943 claim a cryopreservation composition comprising cyclohexanediol such as 1,3-cyclohexanediol or 1,4 cyclohexanediol in an amount from 0.05 to 2.0 M and at least one additional cryoprotectant which list found in claim 14 of the instant invention is found in claim 17 of US application 10/099,943.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the U.S. application 10/099,943, then two different assignees would hold a patent to the claimed invention of U.S. application 10/099,943, and thus improperly there would be possible harassment by multiple assignees.

Claims 11-13, 15-19, 29-32 and 36-44 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-18 of copending Application No. 10/099,943. **This is a new rejection.**

The instant claims are drawn to a cryopreservation compound comprising a cyclohexanediol such as 1, 4 cyclohexanediol and at least one additional cryoprotectant in the concentration of 0.1 to 10 M. Additionally, the cryopreservation compound comprises anti-freeze glycoprotein or an anti-freeze protein. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims 15-18 of U.S. application 10/099,943. That is, the cited claims of U.S. application 10/099,943 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, both the instant invention and the U.S. application 10/099,943 claim a cryopreservation composition comprising cyclohexanediol such as 1,3-cyclohexanediol or 1,4 cyclohexanediol in an amount from 0.05 to

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2.0 M and at least one additional cryoprotectant which list found in claim 14 of the instant invention is found in claim 17 of US application 10/099,943.

Response to Arguments- Double Patenting Rejection

Applicants have argued in the amendment filed 9/29/04 that as US application 10/099,943 is a pending application, the double patenting rejections based upon this application is provisional. Applicants state that they need not further address the provisional obviousness-type double patenting at this time.

The arguments filed 9/29/04 have been considered but are not persuasive. The rejection of will remain until such time as a terminal disclaimer over the claims of the '943 application is filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13, 15, 18, 19, 29-32, 36-39 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 2003/0111638 A1 based upon application 08/943147 now patent number 6,773,877; see entire document) or O'Connell (J Protozool., 1968, 15(4), pages

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719-24; see entire document) in view of Brockbank (Principles of Autologous, Allogeneic and Cryopreserved Venous Transplantation, 1995; see entire document). **This is a new rejection.**

Applicants recite a cryopreservation composition comprising a cyclohexanediol such as 1, 4 cyclohexanediol and at least one additional cryoprotectant in the concentration of 0.1 to 10 M. Additionally, the cryopreservation compound comprises anti-freeze glycoprotein.

Fahy teaches compositions comprising ice-controlling molecules such as 1,3-cyclohexanediol (CHD). Figure 17-18 shows the effect of 1, 3-CHD on cryopreservation using 6% CHD in DMSO and formamide and 15% 1,2 propanediol (propylene glycol) in a Euro-Collins vehicle solution (see e.g. paragraph 0114). In the compositions taught by Fahy, 6% CHD present in the composition is about 0.05 M, DMSO is present in the composition in a concentration of 2.9 M and formamide is present in the composition in a concentration of 2.8 M. Fahy teaches use of cyclohexanetriol as starting material for the production of cyclohexanediol polymers (see e.g. page 8, paragraph 108). For cryopreservation, 3% AFGP is added to 3% CHT (see Figure 16). Upon formation of polymers, the cryopreservation composition would comprise CHD polymers and AFGP.

O'Connell et al teach a composition comprising 4% 1,4 cyclohexanediol or 1,3-cyclohexanediol in complex or semi-synthetic media (see e.g. table 2). The media contains for example 1% sucrose, which is about 0.03M (see e.g. table 1). The cells are contacted with the cryopreservation composition and the temperature is reduced (see e.g. page 720, column 1, paragraph 3).

Neither Fahy nor O'Connell teach the use of cryoprotectants that are selected from the lists recited in claim 11 or alternatively in claim 29.

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Brockbank teaches methods of cryopreservation using compounds with cryoprotective properties. In table 10.1, chemicals with demonstrated cryoprotective activity are identified most of which overlap with the recited cryoprotectants in claim 11 and claim 29. Furthermore, Brockbank teaches that combinations of two cryoprotectants can result in additive or synergistic enhancement of cell survival (see e.g. page 95, paragraph 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute formamide or propanediol in the composition taught by Fahy or sucrose taught by O'Connell et al with the cryopreservation compounds taught by Brockbank because Fahy and O'Connell et al teach that it is within the ordinary skill of the art to cryopreserve cells using cyclohexanediol with a secondary cryoprotectant and because Brockbank et al teach that it is within the ordinary skill of the art to use a number of compounds as cryoprotectants. One would have been motivated to do so in order to receive the expected benefit of obtaining additive or synergistic enhancement of cell survival by the combination of two cryoprotectants as taught by Brockbank et al (page 95, paragraph 2). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 16-17, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 2003/0111638 A1 based upon application 08/943147 now patent number 6,773,877; see entire document) or O'Connell (J Protozool., 1968, 15(4), pages 719-24; see entire document) in view of Brockbank (Principles of Autologous, Allogeneic and Cryopreserved

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Venous Transplantation, 1995; see entire document) further in view of Chao et al (J Exper. Biol. 1996, Vol 199 pages 2071-2076; see entire document). **This is a new rejection.**

Applicants claim a composition comprising cyclohexanediol and an antifreeze protein.

The teachings of Fahy and O'Connell et al and Brockbank are as above except:

Nether Fahy nor O'Connell et al in combination with Brockbank teach addition of antifreeze proteins to cryopreservation compositions.

Chao et al teach the addition of Type I, II and III AFP to human red blood cells (see page 2072, column 2, paragraph 4-5). AFP was effective at protecting against hemolysis at concentrations of between 0.01 mg/ml and 1 mg/ml (see e.g. Figure 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to supplement the composition taught by Fahy or O'Connell et al with the antifreeze proteins taught by Chao et al because Fahy and O'Connell et al teach that it is within the ordinary skill of the art to cryopreserve cells using cyclohexanediol and because Chao et al teach that it is within the ordinary skill of the art to increase cell survival by addition of AFP to the cells. One would have been motivated to do so in order to receive the expected benefit of inhibiting recrystallization and increased survival of cells during freeze-thawing (see Chao et al page 2072, column 1, paragraph 2). Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Response to Arguments

Applicants have argued in the amendment filed 9/29/04 that by amendment of the claims, the rejections based upon Fahy and O'Connell et al have been overcome.

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The arguments filed 9/29/04 have been considered but are not persuasive. In light of the newly applied rejections, the claims have not been found allowable.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

December 12, 2004


GERRY LEFFERS
PRIMARY EXAMINER